PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING

To:
LEE, Young Pil

The Cheonghwa Bldg., 1571-18, Seocho-dong, Seocho-gu,
Seoul 137-874, Republic of KOREA

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing *(day/month/year)*	08 JULY 2004 (08.07.2004)
Applicant's or agent's file reference: NO-20994-PCT	**REPLY DUE** within 2 months from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/KR2003/001449	**22 JULY 2003 (22.07.2003)**	22 JULY 2002 (22.07.2002)

International Patent Classification (IPC) or both national classification and IPC

IPC7 A61K 47/02

Applicant

NANOHYBRID CO., LTD. et al

1. This written opinion is the first (first,etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
   - I [X] Basis of the opinion
   - II [ ] Priority
   - III [ ] Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [X] Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.

   When ? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d)

   How ? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3

   For the form and the language of the amendments, see Rules 66.8 and 66.9

   Also For an additional opportunity to submit amendments, see Rule 66.4

   For an examiner's obligation to consider amendments and/or arguments, seeRule 66.4bis

   For an informal communication with the examiner, see Rule 66.6

   If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 12 NOVEMBER 2004 (12.11.2004)

Name and mailing address of the IPEA/KR
Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon 302-701,
Republic of Korea
Facsimile No. 82-42-472-7140

Authorized officer
KIM, KYOUNG MI
Telephone No. 82-42-481-8161

WRITTEN OPINION

International application No.
PCT/KR2003/001449

I. Basis of the opinion

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:
pages 1 - 17, as originally filed
pages ____, filed with the demand
pages ____, filed with the letter of ____

☒ the claims:
pages 18 , 19, as originally filed
pages ____, as amended (together with any statment) under Article 19
pages ____, filed with the demand
pages ____, filed with the letter of ____

☒ the drawings:
pages 1/5, 3/5, 5/5, as originally filed
pages ____, filed with the demand
pages 2/5, 4/5, filed with the letter of 26/08/2003

☐ the sequence listing part of the description:
pages ____, as originally filed
pages ____, filed with the demand
pages ____, filed with the letter of ____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language English which is

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☒ the language of publication of the international application(under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/ or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

☐ contained inthe international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international applicationas as filed has been furinshed.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages ____

☐ the claims, Nos. ____

☐ the drawings,sheet/fig ____

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box(Rule 70.2(c)).

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."*

WRITTEN OPINION

International application No.
PCT/KR2003/001449

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-15	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-15	NO
Industrial applicability (IA)	Claims	1-15	YES
	Claims		NO

2. Citations and explanations

D1 : JP 13278810 A (2001.10.10.)
D2 : Biomaterials, Vol. 23, pp1981-1987 (2002. 5.)
(D2 문헌은 국제조사보고서에서 인용되지 않은 것이지만 본 견해서 작성에 참조함)

특허청구범위 제1항 내지 제15항은 이트라코나졸, 사이클로스포린, 카르베디올로 이루어진 군으로부터 선택된 약물이 층상형 규산염의 중간에 삽입 또는 표면에 흡착된 혼성체에 관한 것으로 이를 상기 문헌들과 대비하면

1. 신규성

본원발명은 난용성 약물의 용해도를 증가시키고자 하는 발명의 목적과 층상형 규산염에 난용성 약물이 삽입된 혼성체인 점이 D1 문헌과 동일하나 D1문헌의 실시예에는 인도메타신과의 혼성체를 개시하고 있는데 비하여 본원의 약물은 이트라코나졸, 사이클로스포린, 카르베디올이며, D2 문헌에도 약물이 삽입된 몬로릴로나이트가 기재되어 있으나 삽입된 약물이 5-FU로 본원과 상이하므로, 본원의 청구항 제1항 내지 제15항은 D1문헌 및 D2문헌에 의하여 신규성이 인정됩니다. [PCT Article 33(2)].

2. 진보성

D1문헌에는 층상 규산염을 수용액에 분산하고 수난용성 약물이 용해된 유기용매와 혼합한 후 용매를 제거함으로서 수난용성 약물의 용해도가 증진된 조성물이 제조됨을 개시하고 있어서 본원의 혼성체와 동일한 기술적 특징을 갖는 것이며 다만 난용성 약물의 종류에만 차이가 있는 것이나, D1문헌의 명세서에는 항생제, 항고혈압제 등의 다양한 약물이 기재되어 있고, D2문헌에는 5-FU가 흡착 또는 삽입된 몬로릴로나이트를 개시하고 있을 뿐 아니라 양이온성 약물이 몬로릴로나이트의 층 사이에 삽입되는 것이 통상적인 기술이라고 기재되어 있어서,

(Supplemental Box에 계속됨)

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

청구항 제1항 내지 제15항에 기재된 "hybrid"라는 표현은 그 의미하는 바가 불명확하며, 청구항 제8항 내지 제12항의 pH 및 중량% 범위에 대하여 "about"이라는 표현도 명확하지 않습니다.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Box. V.

당업자라면 아민기가 암모니움기로 전환되어 양이온이 되는 이트라코나졸, 사이클로스포린, 카르베디올의 용해도를 증진시키기 위하여 증상 규산염과의 혼성체를 용이하게 도출할 수 있으며, 본원에서 66 wt%의 이트라코나졸 혼성체를 경구투여하였을 때 생체이용율이 증가됨을 나타내는 결과는 기재하고 있으나 이러한 결과만으로 본원에서 특허청구하는 혼성체가 비경구적으로 투여되는 경우에도 D1 및 D2문헌으로부터 예상되지 못하는 현저히 우수한 효과를 나타낸다고 인정할 만한 근거가 없으므로,

본원의 청구항 제1항 내지 제15항은 D1문헌 및 D2문헌에 의하여 진보성이 인정되지 않습니다 [PCT Article 33(3)].

3. 산업상 이용가능성
본원의 특허청구범위 제1항 내지 제15항은 산업상 이용가능성이 있는 발명으로 인정됩니다. [PCT Article 33(4)].